



JPW

**TRANSMITTAL LETTER
(General - Patent Pending)**

Docket No.
UT-0048

In Re Application Of: **Rao et al.**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/502,224	July 22, 2004	Not yet assigned	26259	1632	1620

Title: **Pure Populations of Astrocyte Restricted Precursor Cells and Methods for Isolation and Use Thereof**

COMMISSIONER FOR PATENTS:

Transmitted herewith is:

Courtesy copy of International Preliminary Examination Report

in the above identified application.

- ☒ No additional fee is required.
- ☐ A check in the amount of _____ is attached.
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Jane Massey Licata

Signature

Jane Massey Licata, Reg. No. 32,257

Dated: **August 10, 2005**

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PATENT COOPERATION TREATY

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PCT

COMMUNICATION IN CASES FOR WHICH
NO OTHER FORM IS APPLICABLE

Date of Mailing
(day/month/year)

31 MAY 2005

Applicant's or agent's file reference

UT-0040

REPLY DUE

see paragraph 1 below

International application No.

PCT/US03/02356

International filing date

(day/month/year) 23 January 2003 (23.01.2003)

Applicant

UNIVERSITY OF UTAH RESEARCH FOUNDATION

1. ☐ REPLY DUE within ____ months/days from the above date of mailing



NO REPLY DUE

2. COMMUNICATION:

The International Preliminary Report on Patentability (PCT/IPEA/409) mailed 01 March 2005 did not contain the appropriate information in Box No. V, the "Reasoned Statement" section, and in Box No. VIII, the "Certain Observations" section, and is hereby vacated. The attached corrected PCT/IPEA/409 contains the appropriate information in both sections. No other changes have been made.

Name and mailing address of the IPEA/US

Mail Stop PCT, Attn: IPEA/US
Commissioner for Patents
P.O. Box 1450
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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference UT-0040	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/US03/02356	International filing date (day/month/year) 23 January 2003 (23.01.2003)	Priority date (day/month/year) 23 January 2002 (23.01.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): A01N 63/00, 65/00; C12N 5/00 and US Cl.: 435/325, 424/93.1		
Applicant UNIVERSITY OF UTAH RESEARCH FOUNDATION		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:

a. ☐ (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:

☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application |

Date of submission of the demand 16 September 2003 (16.09.2003)	Date of completion of this report 18 February 2005 (18.02.2005)
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Joseph T. Weitach Telephone No. (571) 272-1600

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4)
- ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☒ the description:

pages 1-20 as originally filed/furnished

pages* NONE received by this Authority on _____

pages* NONE received by this Authority on _____

☒ the claims:

pages 21 and 22 as originally filed/furnished

pages* NONE as amended (together with any statement) under Article 19

pages* NONE received by this Authority on _____

pages* NONE received by this Authority on _____

☐ the drawings:

pages NONE as originally filed/furnished

pages* NONE received by this Authority on _____

pages* NONE received by this Authority on _____

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>NONE</u>	YES
	Claims <u>1-10</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-10</u>	NO
Industrial Applicability (IA)	Claims <u>1-10</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and Explanations (Rule 70.7)

Claims 1-10 lack novelty under PCT Article 33(2) as being anticipated by Alfei et al.

Alfei et al. teach that CD44 positive cells are most likely the precursor cells for astrocytes. Alfi et al. teach that characterization of these cells indicate that the are important in spinal cord development and astroblast formation. Alfi describe at least two different types of CD44 positive cells indicating their importance in for tissue repair and neurogenesis in general.

Claims 1-10 lack an inventive step under PCT Article 33(3) as being obvious over Marret et al and Keller et al (US 5,874,301).

Both Marret et al and Keller et al teach a population of cells that are hyahuron positive, indicating that contain the CD44 receptor which is known to be the hyahuronate receptor (see for example Alfei et al.). Both detail characterization of the cells in vitro and in vivo. Based on the properties of the isolated cells Keller et al. teach that this cell population may have a therapeutic value and propose administering the cells in transplantation protocols into patients in need of astrocytes such as in spinal cord injury.

Claims 1-10 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Isolated population of cell types have a variety of uses, including use in transplantation methodology. In the instant case such products and methods may prove clinically useful after further characterization of the isolated cells and further development of transplantation protocols.

----- NEW CITATIONS -----

CORRECTED

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US03/02356

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1-10 are objected to as lacking clarity under PCT Rule 66.2(a)(v) because the claims are not fully supported by the description. The application, as originally filed, did not describe in enough detail the specific cells encompassed by the claims. It is noted that the claimed cells are at least CD44 positive, but many cells maintain this cell surface receptor. The disclosure fails to describe adequately other characteristics of a CD44 positive cell that provide the unique property of being capable of generating astrocytes but not oligodendrocytes. Further, the claims are drawn specifically to the CD44 positive cell and it is not clear why any CD44 positive cell would not meet the limitations of the claims. The disclosure provides one source and method of isolating CD44 cells but fails to adequately describe a cell sufficiently relative to its claimed properties wherein one could distinguish the claimed cell from any other that is CD44 positive.